DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date FEB 10 2011

From Director, Office of Compliance, WO66-3521/3523
Center for Devices and Radiological Health

Subject Approval Requested for Class I Recall –**ACTION MEMO**
Medtronic SynchroMed Implantable Infusion System

To Director, Center for Devices and Radiological Health
Attn: Jeffrey E. Shuren, M.D., J.D., Director, WO66-5429/5431

Recalling Firm: Medtronic, Inc - Neuromodulation
7000 Central Ave NE
Minneapolis, Minnesota 55432-3568

ISSUE Occurrence of Pocket Fills during refill of Medtronic SynchroMed II and Synchromed EL Implantable Infusion Pumps

Medtronic, Inc. has issued an "Urgent, Medical Device Correction" letter regarding the SynchroMed Implantable Infusion Pump System. The SynchroMed Implantable Infusion pump (infusion pump) is indicated for the delivery of morphine, ziconotide and Lioresal in the treatment of chronic pain, severe chronic pain and severe spasticity. The infusion pumps are also indicated for delivery of floxuridine and methotrexate for the treatment of primary or metastatic cancer. The refill kits are intended for use in refilling implantable infusion pumps.

Events have been reported to Medtronic regarding the inadvertent injection of drug into the patient's subcutaneous tissue during the refill procedure. This inadvertent injection of all or some of the prescribed drug into the patient's subcutaneous tissue instead of the infusion pump's reservoir is called a pocket fill. The health consequences related to a pocket fill include underdose of medication, overdose of medication, confusion, loss of consciousness, respiratory depression, hypotension and death.

BACKGROUND

Between January 2006 and January 2011, the FDA has received a total of 248 Medical Device Reports (MDRs) associated with this failure. Of the reported MDRs, there have been four (4) deaths, 105 serious or life threatening injuries, and eight (8) malfunctions. The firm estimates that the number of pocket fill events through FY2011 will be 47 (about 1 pocket fill per 10,000 refill opportunities). However, because of under reporting, this number could be higher.

The FDA became aware of the pocket fill issue through the Minneapolis District Office on January 6, 2011.

The firm distributed an "Urgent: Medical Device Correction" letter to consignees on January 14, 2011. The notice provided important reminders to consignees about the potential for pocket fills when refilling the implantable infusion pump, recommendations for avoiding pocket fills, and recommendations for patient management. The firm is in the process of updating the pump's labeling to include information related to improper injection of the drug during refill. The firm is not retrieving product from the field or recommending the removal of product in association with this communication. The firm instructed consignees to review the information and complete and return the customer reply card. These actions will not be expected to cause a device shortage.

A Health Hazard Evaluation (HHE) was conducted on February 3, 2011. The District was informed that the recall was a potential Class I and it was recommended that the firm issue a press release. FDA is currently reviewing the firm's draft press release. This recall will appear in the weekly FDA Enforcement Report and be posted on the Med Watch internet site.

DISTRIBUTION

There are a total of 91,369 units in distribution nationwide. The primary users of this device are hospitals, clinics, and patients. This product was distributed from May 1999 to January 2011.

HEALTH HAZARD EVALUATION

A Health Hazard Evaluation (HHE) was conducted on February 3, 2011. It was determined that there is a reasonable probability that the occurrence of a pocket fill during the SynchroMed II or SynchroMed EL refill procedure will cause serious adverse health consequences or death.

RECOMMENDATION

We recommend that the action taken by Medtronic be classified as a Class I recall.

Steven D. Silverman